

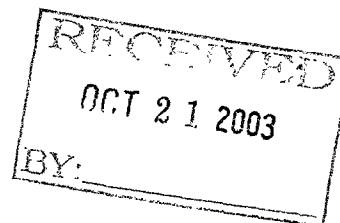
TRONEX

Pharmaceutical Industries

October 16, 2003

7368 '03 NOV -3 21:27

Division of Dietary Supplements
Office of Nutritional Products, Labeling, and Dietary Supplements ONPLDS
U.S. Department of Health and Human Services HHS
U.S. Food and Drug Administration FDA
Center for Food Safety and Applied Nutrition CFSAN
5100 Paint Branch Parkway
College Park, MD 20740
Telephone: 301-436-2375



Dear Sir or Madam:

In compliance with **"Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure"**, Tronex Pharmaceutical Industries as the United States distributor for the product **Puragold®**, is submitting this notification for registration and/or approval. Our contact information is at the bottom of this letter. This product is manufactured in China by the Hong Kong company: PuraPharm International (H.K) Ltd. **Puragold®** has been on the market in Hong Kong and China for many years.

Enclosed you will find 2 copies of our upcoming dietary supplement label and package graphics that we are submitting for the 30-day notification/registration required for new dietary supplements.

Please notify us of any additional information that you require us to submit or of any modifications that are required for the enclosed material.

I, to the best of my knowledge, certify the accuracy of the information in this notice, that it is accurate and complete, and the statements contained within are truthful and not misleading.

Thank you for your kind attention.

Sincerely,

Thomas Y. Chen

Thomas Y. Chen
CEO

cc. Donald Chu, president

975 0162

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13234

86233

TRONEX Pharmaceutical Industries

One Tronex Centre, 3 Luger Road, Denville, NJ 07834

tel: 973-627-3800, fax: 973-625-7630, email: tronexpharmaceutical.com

培力金靈芝™採用六種純天然野生靈芝，以低溫提取濃縮而成，靈芝含量極高。六種野生靈芝均經過DNA基因鑑定，保證其質量及純度。金靈芝™服後不寒不燥，乃靈芝極品中之正宗。

每瓶金靈芝™含標準靈芝精華36克，相等於270克乾天然野生靈芝。

成份：六種天然野生靈芝精華。

用法：每日1次，每次1至2粒。

包裝：每瓶90粒，淨重36克。

儲存：置於陰涼乾燥處。

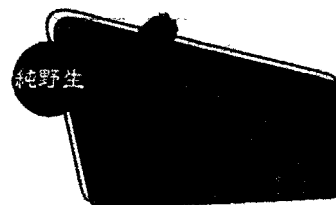
注意：孕婦須遵照醫生指示服用。
請將此放在兒童無法觸及處。

培力(香港)健康產品有限公司產品

*以上數據未經食品藥物管理局評估。
本品並無用作診斷、醫治、治療預防任何疾病之靈。

90粒裝

270克野生靈芝



PURAGOLD
NATURAL & WILD

集六芝精華 極品之正宗
The Original Premium Lingzhi
Herbal supplement

PuraPharm PURAGOLD™ is made from the essence of SIX types of Natural wild Lingzhi using low temperature extraction method. Standardized by proprietary DNA fingerprinting technology for the accurate strains of Lingzhi, PURAGOLD™ surpasses other Lingzhi products currently available in the market in both quality and effectiveness.

PURAGOLD™ contains 36g of standardized Lingzhi extract equivalent to 270g of dried natural wild Lingzhi.*

Ingredients: Standardized Lingzhi extract

Dosage: Once per day, 1 to 2 capsule(s) each time

Packaging: Each bottle contains 90 capsules

Net Weight: 36g

Storage: Store in a cool and dry area

Warning: Pregnant or nursing women should consult their healthcare professional before taking any dietary supplement. Keep out of reach of children.

* These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

© A product of PuraPharm International (HK) Ltd.
Distributed by: PuraPharm International (HK) Ltd.
Dunelm, NJ 07034 USA

PuraPharm

90 Capsules

270g Dried Natural Wild Lingzhi

純野生

PURAGOLD
NATURAL & WILD

PuraPharm

純野生

PURAGOLD
NATURAL & WILD

集六芝精華 極品之正宗
The Original Premium Lingzhi

Herbal supplement

90粒裝

270克野生靈芝



4 895024 200385

PuraPharm

A Product of PuraPharm International (HK) Ltd.
培力(香港)純地產產品有限公司產品
Distributed by: Thomas Pharmaceutical Industries
Dunelm, NJ 07834, USA

PURAGOLD™ is a registered trademark of PuraPharm International (HK) Ltd. 中國註冊商標及商標局註冊商標。

培力金靈芝™採用六種純天然野生靈芝，以低溫提取濃縮而成，靈芝含量極高。六種野生靈芝均經過DNA基因鑑定，保證其質量及純度。金靈芝™服後不寒不燥，乃靈芝極品中之正宗。

每瓶金靈芝™含標準靈芝精華36克，相等於270克乾天然野生靈芝。

成份：六種天然野生靈芝精華。

用法：每日1次，每次1至2粒。

包裝：每瓶90粒，淨重36克。

儲存：置於陰涼乾燥處。

注意：孕婦須遵照醫生指示服用。請將此放在兒童無法觸及處。

補充資料：	
每份份量：1粒	
每瓶淨重	%每日所需量
六種天然野生靈芝精華...400mg	**
**每日所需量未確定。	

其他成份：澱粉

*以上數據未經食品與藥物管理局評估。本品並非用作診斷、醫治、治療或預防任何疾病之意。

PuraPharm PURAGOLD™ is made from the essence of SIX types of Natural Wild Lingzhi using low temperature extraction method. Standardized by proprietary DNA fingerprinting technology for the accurate strains of Lingzhi, PURAGOLD™ surpasses other Lingzhi products currently available in the market in both quality and effectiveness.

Each bottle of PURAGOLD™ contains 36g of standardized extract equivalent to 270g of dried natural wild Lingzhi.*

Ingredients : Standardized Lingzhi extract
Dosage : Once per day, 1 to 2 capsule(s) each time

Packaging : Each bottle contains 90 capsules
Net Weight : 36g

Storage : Store in a cool and dry area
Warning : Pregnant or nursing women should consult their healthcare professionals before taking any dietary supplement. Keep out of reach of children.

Supplement Fact	
Serving Size 1 capsule	
Each Capsule Contains	%Daily Value
Standardized Lingzhi extract ... 400mg	**
**Daily Value not established.	

Other ingredient: Corn starch

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

PuraPharm

純野生

PURAGOLD
NATURAL & WILD

集六芝精華 極品之正宗
The Original Premium Lingzhi

Herbal supplement

90 Capsules

270g Dried Natural Wild Lingzhi

Lingzhi - The Superior Herb

Traditionally, Chinese medicine was divided into three classes. The superior class, like Lingzhi and Ginseng, must not be intrusive, can promote health and longevity and causes no side effects through continuous use. It can also help to maintain overall bodily functions and strengthen the natural healing abilities of the body. The middle class of medicine is for the prevention of diseases and can provide energy to the body.

The lower class of medicine is for curing diseases and must not be used for prolonged period.

The oldest and the most influential Chinese medical directory, the "Shen Nong's Medica" and "The Chinese Herbal Materia Medica" both rated Lingzhi as superior and the best among all other Chinese herbs.

What Makes Up Lingzhi

Lingzhi contains Polysaccharides, Triterpenoids, Adenosine and other trace elements, that help us improve the functions of the immune system, good capillary blood circulation, and to promote a healthy metabolism.

PURAGOLD® Lingzhi Capsules

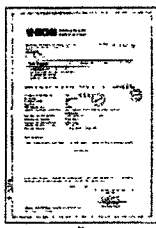
PURAGOLD® has the following unique benefits:

A Product of Joint Research with The Institute for Advancement of Chinese Medicine of the Hong Kong Baptist University. There are many types of Natural and Wild Lingzhi. To ensure the quality of the product, all ingredients must be tested scientifically to safeguard its authenticity and quality. PURAGOLD® is the only Lingzhi product standardized by proprietary DNA fingerprinting technology developed by The Institute for Advancement of Chinese Medicine of the Hong Kong Baptist University, thereby ensuring the authenticity, purity and quality of the product.

Safety Assurance

PURAGOLD® is tested scientifically by worldly renowned testing laboratories and has obtained certificates on heavy metal, microbial and toxicity. Its safety and reliability are therefore guaranteed.

GMP (Good Manufacturing Practice) Standard PURAGOLD® is manufactured under the international GMP (Good Manufacturing Practice) standards to guarantee the safety and reliability of the product.



PURAGOLD® obtains testing certificate released by worldly renowned testing laboratory.

Essence of Six Species of Lingzhi

According to the oldest and the most influential Chinese medical directory, the "Shen Nong's Medica" and "The Chinese Herbal Materia Medica", Lingzhi is classified into six categories according to their shapes and colors, namely red, purple, green, white, black and yellow. Different Lingzhi nourishes different parts of the body: red Lingzhi for the heart, purple Lingzhi for the joints, green Lingzhi for the liver, white Lingzhi for the lung and skin, black Lingzhi for the kidney and the brain, while yellow Lingzhi for the spleen.

After years of extensive clinical research, the inventor of PURAGOLD® revolutionized the production of Lingzhi products years ago by combining different types of Lingzhi into one product. PURAGOLD® was precisely formulated according to the Chinese theory of the five paths. Combining with the newest low temperature extraction technology, PURAGOLD® can effectively nourish different parts of the body and is the best and the most effective Lingzhi product in the market.

Natural and Wild Lingzhi

Lingzhi is very selective of its habitat except the red and the purple Lingzhi. Most wild Lingzhi needs an almost perfect environment to germinate. Certain species of Lingzhi require very specific environmental conditions such as unpolluted air, high altitude, the correct seasonal changes, etc., for them to grow to maturity successfully. Consequently, most species of Lingzhi cannot be cultivated artificially.

Natural and Wild Lingzhi are constantly subject to the challenges of the harsh natural environment. Triggered by the surrounding antigens, Lingzhi will develop their own antibodies to protect themselves against the harsh natural environment using their natural defensive mechanism. These antibodies cannot be found in cultivated Lingzhi. Medical researchers nowadays commended highly the benefits of these antibodies have on the human body. Since artificial cultivated Lingzhi is cheaper, most Lingzhi products available in the market use this instead of the natural and wild one. However, PuraPharm International (H.K.) Ltd. will not compromise on the quality of its products. PURAGOLD® is made of 100% grade one wild Lingzhi. Therefore, PURAGOLD® excels among all Lingzhi products currently available in the market.

Most Potent Lingzhi with Recommended 3 Months Consumption Pack

Using improved extraction technology, PURAGOLD® contains the highest concentration of Lingzhi per capsule. PURAGOLD® contains 2-3 times the content of Polysaccharides and Triterpenoids than most products in the market. One bottle of PURAGOLD® contains 270 grams of premium grade dried wild Lingzhi (each capsule contains 3.0 grams).

PURAGOLD® contains the highest amount of Wild Lingzhi per capsule than all other available products to date. You only need to take one capsule a day to get the benefit. One bottle of PURAGOLD® will last you 3 months.

Improved Extraction Process

Processed using the latest low temperature extraction and vacuum drying method, PURAGOLD® maintains all the nutrients of the original herb, thus ensuring the highest product quality.

Ingredients & Dosage

One bottle of PURAGOLD® contains 90 Lingzhi capsules equivalent to 270g of premium grade dried wild Lingzhi. PURAGOLD® has the highest content of Lingzhi among all other Lingzhi products. PURAGOLD® Lingzhi capsule is suitable for male and female over 5 years old.

Ingredients : 99% six species of Natural and Wild Lingzhi: red, purple, green, white, black and yellow Lingzhi, 1% starch. Each bottle contains the equivalent of 270g of premium grade dried wild Lingzhi.

Dosage : Once per day, 1-2 capsule(s) each time.

Packaging : Each bottle contains 90 capsules, net weight 36g.

Storage : Store in a cool and dry area.



PURAGOLD® contains six categories of natural and wild Lingzhi: red, purple, green, white, black & yellow Lingzhi.

PuraPharm 普力華

Hong Kong Office : PuraPharm International (H.K.) Ltd.
Suites 4103-08, Jardine House, 1 Connaught Place, Central, Hong Kong
Tel : (852) 28401840 E-mail : info@purapharm.com
Fax : (852) 2480 0778 Website : www.purapharm.com

Distributed by : Tronex Pharmaceutical Industries, One Tronex Centre,
3 Luger Road, Denville, NJ 07834, U.S.A.
Tel : 973-627-3800 E-mail : products@tronexpharmaceutical.com
Fax : 973-627-8518 Website : www.tronexpharmaceutical.com

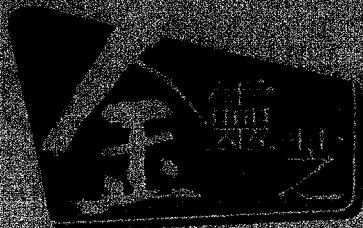
* If you would like to enjoy future benefits on product purchases, please complete the form below and mail to Tronex Pharmaceutical Industries, One Tronex Centre, 3 Luger Road, Denville, NJ 07834, U.S.A.

Name : _____
Sex : M/F Date of Birth: ____ (YY) ____ (MM) ____ (DD)
Occupation: _____ Phone No.: _____
Mailing Address: _____

E-mail Address: _____

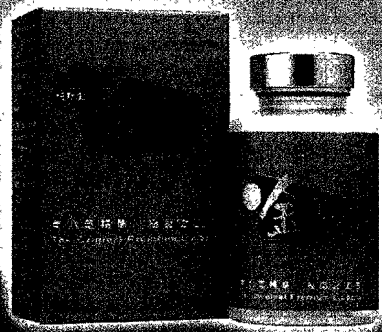
*All information is strictly confidential
These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease

PuraPharm 純力



PURAGOLD
NATURAL & WILD

集六種野生靈芝精華
經DNA基因鑑定



集六種精華 極品之正宗

靈芝-上藥中之極品

自古以來，中藥被分為上藥、中藥、下藥三個等級；上藥如靈芝、人參等，乃君臣養生之藥，可以長期服用，全無副作用，且能立刻調節身體的異常，使體質正常化。中藥是預防疾病，保健強身之藥，下藥則為對症治療之藥，不可長期服用。根據我國經典醫學巨著《神農本草經》和《本草綱目》，靈芝是排列在最高的位置，為上藥中之極品。

靈芝的成份

靈芝的主要成份為多醣體、三萜類、鵝甘類及多種微量元素等，能大大提高人體的免疫力；促進血液循環及新陳代謝。

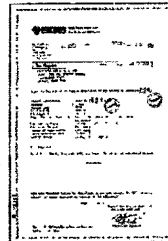
金靈芝™ 靈芝膠囊

金靈芝™ 靈芝膠囊具有以下獨特之處：

野生靈芝品種繁多，要確保品質純正，定要經過多項高科技方法鑑定其品質。金靈芝™ 膠囊是經香港浸會大學中醫藥研究所DNA基因鑑定的靈芝產品，保證其靈芝品種、質量及純度真確，不含雜質，絕對可靠。

金靈芝™ 膠囊經多間國際公證行化驗，獲發重金屬、微生物及藥物殘留等安全測試之合格證書，保證絕對安全可靠。

金靈芝™ 膠囊是按GMP (優良藥品製造規範) 生產模式製造而成，保證產品安全可靠，男女老幼，皆可服用。



金靈芝™ 獲得世界認可的國際公證行所發出之安全測試證書

根據中國醫學巨著《神農本草經》及《本草綱目》的記載，靈芝依其外形分為赤、紫、青、白、黑、黃等六芝，每種靈芝各具療效：赤芝主治心臟，白芝主治肺，青芝主治肝，黑芝主治腎，黃芝主治脾。金靈芝™ 膠囊乃集合以上六種純天然野生靈芝，根據中醫的五行哲理，以最合理及最精確的改良組成比例，配合最新的低溫提取濃縮技術，經過多年的反覆測試成功研製而成的，能更有效地提供人體各部份不同的需要，發現今最新及最有功效的多種野生靈芝產品。

野生靈芝對其生長環境極其選擇，所有生態環境必須符合其生長的要求始能孕育出健康的靈芝。其生態條件包括空氣的質素，海拔的高度以至四季氣候的變化等都要吻合，否則成功生長的機會不高。故此野生靈芝十分珍貴，採用之成本亦極其高昂，同時亦難以人工培植。天然野生靈芝因長期受到野外環境的挑戰，在其生長的過程中自然產生出植物的抗體，此抗體是人工培植的靈芝所缺少的，而現代的醫學家卻非常重視此等抗體對人體的益處。但為配合經濟原則，現時市面上出售的大部份靈芝產品多為人工培植的。相反，金靈芝™ 膠囊卻是不惜工本，全部由百份百一級天然野生靈芝精製而成，能夠全面發揮天然野生靈芝之療效。

野生靈芝成份含量最高，一瓶即可服用3個月

金靈芝™ 膠囊是經改良提取濃縮科技製成，使靈芝成份更加濃縮，其三萜類及多醣體含量為市面上一般靈芝產品之2-3倍，更易被人體各部份所吸收及發揮其功效。每瓶金靈芝™ 膠囊含相等於270公克六種純野生靈芝(每顆膠囊含3公克)，是目前市面上靈芝保健品中含靈芝量最高的產品。每日只需服用1顆，即已符合專家建議之攝取量。一瓶90粒，足可服用3個月。

金靈芝™ 膠囊

金靈芝™ 膠囊以新研發的低溫提取及低溫真空乾燥技術製成，能保留天然野生靈芝之養份。

成份和用法

每樽90粒裝金靈芝™ 膠囊含相等於270公克的特級天然野生靈芝，是目前市面上靈芝含量最高、品質最佳之天然保健食品。金靈芝™ 膠囊安全可靠，五歲以上男女，皆可服用。

成份：99%六種純天然野生靈芝，分別為赤芝、紫芝、青芝、白芝、黑芝和黃芝；1%澱粉。每瓶90粒裝金靈芝™ 膠囊含相等於270公克的特級天然野生靈芝。

用法：每日1次，每次1-2粒。

包裝：每瓶90粒，淨重36公克。

儲存：置於陰涼乾燥處。



金靈芝™ 由六種天然野生靈芝所組成，分別是赤、紫、青、白、黑及黃芝。

PuraPharm 純力

製造商：純力(香港)健康產品有限公司
香港中環康樂廣場1號怡和大廈4103-08室
電話：2840 1840 電子郵件：info@purapharm.com
傳真：2840 0778 網址：www.purapharm.com

*想享受日後購物優惠，請填妥以下表格，寄回Tronex Pharmaceutical Industries, One Tronex Centre, 3 Luger Road, Denville, NJ 07834, U.S.A.
電話：973-627-3800 傳真：973-627-8518

姓名：_____

性別：男/女 出生日期：_____年_____月_____日

職業：_____ 聯絡電話：_____

聯絡地址：_____

電郵地址：_____

*所有資料絕對保密

以上數據未經食品與藥物管理局評估，本品並無用作診斷、醫治、治療或預防任何疾病之重。